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Inventor: Tracey C. Slemker

Attorney

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Title: Valve Assembly For A Prosthetic Limb

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CERTIFICATE OF MAILING UNDER 37 CFR §1.8 (a)

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first-class mail in an envelope addressed to Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*Sheri L. Burke*

Sheri Burke

Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Dear Sir:

Raymond Francis declares as follows:

1. I am currently the Chief Prosthetist for Ohio Willow Wood, the owner of the above-identified patent application.

2. I was awarded a certificate in Prosthetics from New York University in 1960. I received a board certification from the American Board for Certification in Prosthetics and Orthotics, Inc., in 1967, and I am licensed by the State of Ohio Board of Orthotics, Prosthetics, and Pedorthotics.
3. I am a member of the American Academy of Orthotics and Prosthetics. I served as Region III Director of the American Orthotic and Prosthetic Association from 1975 to 1977.
4. From 1958 to 1966 I was employed as a prosthetic technician and/or as a prosthetic maker. From 1966 until present, I have worked as a prosthetist.
5. In addition to my work as a prosthetist, I also served as CEO of a prosthetics company from 1968 to 1997.
6. I have made numerous presentations, and have published a plurality of articles relating to the field of prosthetics, including presentations and articles relating specifically to prosthetic suspension techniques, and the use of liners.
7. I have taught various seminars at Ohio Willow Wood, as well as given academic instruction to prosthetic undergraduates at numerous colleges and universities across the country.
8. As a prosthetist, I am skilled in the making and fitting of prosthetics. To that end, I am required to be familiar with the various technologies used in prosthetics, including, but not limited to, fitting methods, materials, and suspension techniques and devices. I have worked with many different prosthetic technologies throughout my career.
9. Prior to the 1990's, I am unaware of the existence of any liner for use with a prosthesis employing a suction suspension system. Rather, prior to this time, prostheses employing suction suspension relied primarily on contact between the skin of the amputee's residual limb and the interior surface of the prosthetic socket to ensure a secure fit.
10. In approximately the mid-1990's, the first liner for use with a below-knee (BK) prostheses employing a suction suspension system was introduced. This liner was disfavored because it required internal lubrication to allow receipt of the amputee's residual limb, as well as external lubrication to allow the liner to slide into the socket of the prosthetic limb. Additionally, the socket design adopted for use with this liner made use of a one-way expulsion valve attached to a side of the socket, which one-way valve required an externally-located tube. This combination of socket and liner was problematic, because air could become trapped below the residual limb during the donning of the prosthesis, the one-

way valve frequently became clogged by the lubricant on the outside of the liner, and the external tube was cosmetically unappealing.

11. In approximately the mid-1990's, a liner similar to the liner described in paragraph 10 was also developed for use with above-knee (AK) prostheses employing a suction suspension system. The same problems described in paragraph 10 with respect to the BK liner, were also inherent to this AK liner.

12. An acceptable liner for use with BK prostheses employing suction retention was developed in the late 1990's.

13. Use of liners with AK prostheses employing suction retention did not gain acceptance until approximately 2001.

14. Prior to the invention described in the above-identified patent application, I am unaware of any suction-based prosthetic retention system having an integrated valve system and also specifically designed to allow for use with a liner-covered residual limb.

15. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Date: August 28, 2003

By: Raymond Francis, CP  
Raymond Francis, CP